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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/623,533	09/05/2000	Dominique P. Bridon	REDC-1510USA	3921

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EXAMINER

PARKIN, JEFFREY S

ART UNIT PAPER NUMBER

1648

DATE MAILED: 06/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/623,533

Applicant(s)

BRIDON ET AL.

Examiner

Jeffrey S. Parkin, Ph.D.

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 03 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 March 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,4,6,19-21,31,36-39,52,53 and 55 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,4,6,19-21,31,36-39,52,53 and 55 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 01/12/06
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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Serial No.: 09/623,533
Applicants: Bridon, D.P., et al.

Docket No.: REDC-151USA
Filing Date: 09/05/00

Detailed Office Action

Status of the Claims

Acknowledgement is hereby made of receipt and entry of the amendment received 15 March, 2005. Claims 1, 3, 4, 6, 19-21, 31, 36-39, 52, 53, and 55 are pending in the instant application.

37 C.F.R. § 1.98

The information disclosure statement filed 13 January, 2005, has been placed in the application file and the information referred to therein has been considered.

35 U.S.C. § 112, Second Paragraph

Claims 1, 3, 4, 6, 19-21, 31, 36-39, 52, 53, and 55 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Two separate requirements are set forth under this statute: (1) the claims must set forth the subject matter that applicants regard as their invention; and (2) the claims must particularly point out and distinctly define the metes and bounds of the subject matter that will be protected by the patent grant. The claims have been amended to recite that the peptides of interest are now covalently bonded to a "blood component". The reference to a blood component is vague and indefinite since the precise structural characteristics of said "component" are not clearly set forth. Moreover, the disclosure fails to provide a detailed definition for the term. For instance, does it reference antibodies, serum proteins, lipids, or other molecules? Thus, it is not readily manifest to the skilled artisan which molecules are encompassed by the claim language.

35 U.S.C. § 103(a)

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. § 103(c) and potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103(a).

Claims 1, 3, 4, 6, 19-21, 31, 36-39, 52, 53, and 55, are rejected under 35 U.S.C. § 103(a) as being unpatentable over Bolognesi et al. (1996) in view of Tolman et al. (1993), and further in view of Patrick et al. (1987). Tolman and colleagues disclose the preparation of immunoconjugates comprising HIV undcapeptides and a carrier protein (OMPC). The authors reported

that "3-Maleimidopropionylation of the Nle amino group of the cyclic peptides gave an electrophilic tether which captured a thiol group from a thiolated carrier protein, OMPC" (see abstract, p. 455). The authors further added that these conjugates had suitable physical properties and were stable. This teaching does not disclose the preparation of the claimed modified peptides.

Patrick and colleagues disclose methods for conjugating polypeptides to larger carrier proteins such as bovine serum albumin (BSA). BSA appears to meet all the limitations of a blood component.

However, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to modify the antiviral peptides provided by Bolognesi et al. (1996), to include succinimidyl- or maleimido-containing reactive groups, as described by Tolman et al. (1993), since these peptides would readily form stable conjugates with known carrier molecules. One of ordinary skill in the art would have been motivated to make said chemical modifications because Tolman et al. (1993) clearly disclose that said modifications would produce peptide conjugates with suitable physical properties. Moreover, one of ordinary skill in the art would have been motivated to conjugate said modified polypeptides to a well-known carrier protein such as BSA, to enhance the half-life of the peptide. Thus, both the motivation and a reasonable expectation of success were present in the prior art.

Response to Arguments

Applicants traverse and submit that all of the claimed limitations are not taught in the prior art and that the prior art fails suggest or provide a sufficient motivation to arrive at the claimed invention. Applicants' arguments have been carefully considered but are not deemed to be persuasive. The prior art

clearly teaches peptide modifications, specifically those incorporating succinimidyl- or maleimide-containing groups, are useful for conjugating polypeptides to carrier molecules. The prior art also clearly provides carrier proteins that are "blood components" and teaches that conjugating polypeptides to said carrier proteins makes them more stable and immunogenic.

Additional Prior Art

As previously set forth, the following prior art, which was not relied upon in the office action, is considered germane to applicants' disclosure:

- Marburg, S., et al., 1996, *Introduction of the maleimide function onto resin-bound peptides: a simple, high-yield process useful for discriminating among several lysines", Bioconjugate Chem. 7:612-616.
- Bayer, E. A., et al., 1985, *3-(N-Maleimido-propionyl) Biocytin : a versatile thiol-specific biotinylating reagent*, Anal. Biochem. 149:529-536.
- Ali, M. S., and S. M. Quadri, 1996, "Maleimido derivatives of diethylenetriaminepentaacetic acid and triethylenetetraaminehexaacetic acid: their synthesis and potential for specific conjugation with biomolecules", Bioconj. Chem. 7:576-583.
- Miyazaki, W., et al., U.S. Patent No. 4,536,391, issued 20 August, 1995.
- Chorev, M., U.S. Patent No. 5,242,680, issued 07 September, 1993.

Finality of Office Action

Applicants' amendment necessitated any and all new grounds of rejection. Accordingly, **THIS ACTION IS MADE FINAL**. See M.P.E.P.

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a). A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

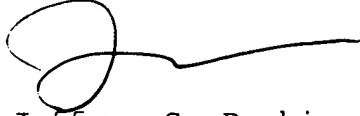
Correspondence

Any inquiry concerning this communication should be directed to Jeffrey S. Parkin, Ph.D., whose telephone number is (571) 272-0908. The examiner can normally be reached Monday through Thursday from 10:30 AM to 9:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, James C. Housel, can be reached at (571) 272-0902. Direct general status inquiries to the Technology Center 1600 receptionist at (571) 272-1600. Formal communications may be submitted through the official facsimile number which is (703) 872-9306. Hand-carried formal communications should be directed toward the customer window located in Crystal Plaza Two, 2011 South Clark Place, Arlington, VA. Applicants are directed toward the O.G. Notice for further guidance. 1280 O.G. 681. Informal communications may be submitted to the Examiner's RightFAX account at (571) 273-0908.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Serial No.: 09/623,533
Applicants: Bridon, D.P., et al.

Respectfully,

A handwritten signature in black ink, consisting of a large, stylized 'J' followed by a horizontal line extending to the right.

Jeffrey S. Parkin, Ph.D.
Primary Examiner
Art Unit 1648

30 May, 2005